UE CONFORMITY DECLARATION

CE

PRODUCT	**LB**
MANUFACTURER PART NUMBER	S080
OTHER NAMES	LEVIA BASCULANTE – LEVIA KID – LEVIA BASCULANTE KID – LBK – LB DYNAMIC
INTENDED USE	The product is intended to be used for alleviation or compensation for an injury or disability. Particularly the wheelchair is intended to be used by those groups of users with temporary or permanent mobility difficulties confined to a sitting position who need to move in mostly indoor environments.
MANUFACTURER	**Neatech.it s.r.l.** via Antonio de Curtis 4/A – 80040 Cercola (NA) – Italia Tel. +39 081 5551946 – info@neatech.it – www.neatech.it P. IVA IT04812481218 – REA NA 715393

As for the product identified above, the manufacturer declares following statements.

- The product meets the applicable essential requirements specified in Annex I of the European Regulation 2017/745.
- The satisfaction of mentioned requirements is assessed with the use of harmonized standards following indications in art. 8 of mentioned Regulation.
- According to criteria of Annex VIII of mentioned Regulation, the product is classified as a **class I medical device** (rule1).
- The product complies with the following technical standards (original test reports are kept at the manufacturer's address):
  - EN 12182:2012;
  - EN 12183:2014 – Tested at TUV Rheinland in Netherland accredited for this test according ISO 17025 and was judged compliant with the applicable requirements of the standard;
  - ISO 7176-19:2008 – Rigid Chassis – Tested at Dahl Engineering in Denmark (CRASH TEST – 4 POINTS TIE-DOWN);
  - ISO 7176-19:2001 – Foldable Chassis – Tested at Millbrook in England (CRASH TEST – 4 POINTS TIE-DOWN).
- A risk analysis was developed for the product in accordance with EN ISO 14971 taking into account all the possible options, variations and accessories described in the order form and in the manual.

NAME	Raffaele Grosso
TITLE	CEO
ON BEHALF OF	Neatech.it s.r.l.
PLACE – DATE	Cercola (NA) Italia, 2021-02-15
SIGNATURE	

NEATECH.IT s.r.l.
Via A. De Curtis, 4 - 80040 Cercola (Na)
Tel. 081 5551946 - Telefax. 081 5552522
P.iva: 04812481218